IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF OREGON

ASHLEY RAE BOYD, an individual,

Plaintiff,

v.

ALLERGAN PLC, a foreign corporation, **ALLERGAN, INC.,** a foreign corporation, **ALLERGAN USA, INC. F/K/A INAMED CORPORATION F/K/A MCGHAN MEDICAL CORPORATION,** a foreign corporation,

Defendants.

Case No. 6:22-cv-01808-MC

OPINION AND ORDER

MCSHANE, Judge:

Plaintiff Ashley Boyd claims that Defendant Allergan USA, Inc. designed, produced, and sold breast implants that failed to meet the requirements for the device set forth by the Food and Drug Administration (FDA). As a result, she suffered injuries. Plaintiff brings state-law claims for negligence, negligence *per se*, and products liability. Because Plaintiff fails to articulate a plausible claim the Defendant failed to meet the federal requirements for the device or deviated from the device's pre-market approval, Defendant's Motion to Dismiss (ECF No. 8) is GRANTED.

BACKGROUND

Plaintiff received McGhan® Style 20 Silicone-Filled breast implants in 2006. Def.'s Notice of Removal Ex. A, ¶ 27, ECF No. 1-1. McGhan designed, produced, and sold plastic and

reconstructive surgery products in the United States and Canada. *Id.* ¶ 6. McGhan changed its name to Inamed Corporation in 1986, and Defendant bought Inamed Corporation in March of 2006. *Id.* ¶ 7.

One of Plaintiff's implants ruptured, resulting in both of her implants being surgically removed. *Id.* ¶ 30. Plaintiff alleges that Defendant's breast implants gave her Lupus and damaged her right eye. *Id.* ¶ 82.[1]

STANDARDS

To survive a motion to dismiss under Fed. R. Civ. P. 12(b)(6), a complaint must contain sufficient factual matter that "state[s] a claim to relief that is plausible on its face." *Bell Atl.Corp. v. Twombly*, 550 U.S. 544, 570 (2007). A claim is plausible on its face when the factual allegations allow the court to infer the defendant's liability based on the alleged conduct. *Ashcroft v. Iqbal*, 556 U.S. 662, 663 (2009). The factual allegations must present more than "the mere possibility of misconduct." *Id.* at 678.

When considering a motion to dismiss, the court must accept all allegations of material fact as true and construe those facts in the light most favorable to the non-movant. *Burget v. Lokelani Bernice Pauahi Bishop Tr.*, 200 F.3d 661, 663 (9th Cir. 2000). But the court is "not bound to accept as true a legal conclusion couched as a factual allegation." *Twombly*, 550 U.S. at 555. If the complaint is dismissed, leave to amend should be granted unless "the pleading could not possibly be cured by the allegation of other facts." *Doe v. United States*, 58 F.3d 494, 497 (9th Cir. 1995).

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[1] Plaintiff does not specify in her complaint when she had the implants removed, nor when she discovered the listed injuries.

DISCUSSION

I. Medical Device Amendment & Preemption

The breast implants designed, manufactured, and sold by Defendant are Class III medical devices, which received pre-market authorization ("PMA") from the FDA. Def.'s Notice of Removal Ex. A, ¶ 22. The Medical Device Amendment ("MDA") to the Food, Drug, and Cosmetic Act gives the FDA oversight over new medical devices. *Id.* ¶ 16. The MDA splits medical devices into three categories. 21 U.S.C. § 360c(a). Class III medical devices, the class of medical devices at issue here, are "purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, or presents a potential unreasonable risk of illness or injury." *Id.* § 360c(a)(1)(C)(ii).

The MDA expressly preempts state regulation of Class III medical devices because of the oversight provided, and requirements imposed, by the FDA. *Weber v. Allergan, Inc.*, 940 F.3d 1106, 1110-11 (9th Cir. 2019). FDA requirements for a particular Class III medical device are "established by the FDA's pre-market approval." *Weber*, 940 F.3d at 1111. The express preemption provision of the MDA states that:

> no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement--
>
> > (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
> >
> > (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a). In other words, the MDA expressly preempts "state law claims challenging the safety and effectiveness of a Class III medical device that had received pre-market approval from the FDA." *Weber*, 940 F.3d at 1111 (citing *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 321-25 (2008)). However, the MDA "does not prevent a State from providing a damages remedy for

claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements." *Riegel*, 552 U.S. at 330. Ultimately, to survive preemption, "a plaintiff must show that the defendant deviated from a particular pre-market approval or other FDA requirement applicable to the Class III medical device." *Weber*, 940 F.3d at 1112.

II. State-law claims

The Court finds that Plaintiff failed to state a plausible claim that Defendant violated a federal requirement. Most of Plaintiff's complaint contains conclusory statements rather than factual allegations. For example, Plaintiff alleges that the implants were "defective, dangerous and adulterated upon manufacture as they were contaminated and were manufactured with nonconforming materials and uncertified components in violation of the PMA specifications and regulatory requirements, resulting in product failure and serious injury to Plaintiff." Def.'s Notice of Removal Ex. A, ¶ 53. Plaintiff, however, failed to provide basic facts such as the source of contamination, or what specific nonconforming materials Defendant manufactured its breast implants with. Plaintiff also failed to allege which PMA specification or regulatory requirement Defendant allegedly violated. The mere allegation that Defendant "violated FDA regulations" fails to state a plausible claim. *In re Medtronic, Inc. Sprint Fidelis Leads Prod. Liab. Litig.*, 592 F. Supp. 2d 1147, 1158 (D. Minn. 2009) (*aff'd* 623 F.3d 1200 (8th Cir. 2010).

Plaintiff recites similar conclusions, listing FDA requirements and claiming Defendant violated them, throughout her complaint without providing a factual basis for such conclusions. To survive a motion to dismiss, a plaintiff must establish the basis for their claim and "a formulaic recitation of the elements of a cause of action" does not suffice. *Twombly*, 550 U.S. at 555. And, in order "to survive MDA preemption, a plaintiff cannot simply demonstrate a defect or a malfunction and rely 'on *res ipsa loquitur* to suggest only that the thing speaks for itself.'" *Weber*,

940 F.3d at 1112 (cleaned up) (quoting *Funk v. Stryker Corp.*, 631 F.3d 777, 782 (5th Cir. 2011)). Simply alleging that Defendant's product was defective and, as a result, Defendant must have violated federal requirements is not enough to establish a plausible claim.

While Plaintiff does provide some factual allegations in her complaint, she ultimately fails to provide sufficient facts to plausibly establish that Defendant violated a federal requirement. Plaintiff alleges that she:

> was not advised, and had no independent knowledge that:[2]
>
> a. A significant risk of rupture of the breast implant; or
> b. She might need future surgery to remove the implants in the future; or
> c. She might need future surgery/chemotherapy and radiation, or
> d. She might need future imaging and/or diagnostic procedures to check for, or evaluate rupture failure or failure in her body; or
> e. The chemicals with which Defendants fill the McGhan Breast Implants contains compounds which are toxic to the human body[.]

Def.'s Notice of Removal Ex. A, ¶ 29.

These allegations, however, are directly contradicted by FDA documents, including Defendant's PMA and warnings provided to patients and doctors.[3] Defendant's "Directions for Use" document directs doctors to warn patients (1) about the risk of rupture, (2) that "[i]mplants

[2] The Court assumes that Plaintiff is alleging she was unaware of these alleged risks because Defendant failed to include these warnings in its product labeling. If, instead, Plaintiff is alleging that her doctor failed to inform her of these risks, the allegations would appear to be irrelevant in claims, like these, against the product manufacturer.

[3] Defendant made a request, unopposed by Plaintiff, that the Court take judicial notice of several FDA approved and published documents. Def.'s Req. for Judicial Notice, ECF No. 9 ("RJN"). These documents include the FDA's PMA letter for Defendant's breast implants, a patient pamphlet titled "Important Information for Women About Breast Augmentation with INAMED® Silicone-Filled Breast Implants," and instructions for doctors titled "Directions for Use." *Id.* at 3. Generally, a court may take judicial notice of "matters of public record" under Federal Rule of Evidence 201 so long as the facts are not subject to reasonable dispute, are incorporated into the complaint, and are from sources whose accuracy cannot be reasonably questioned. *Munson v. Wells Fargo Bank*, 2018 WL 6515131, at *2 (D. Or. Dec. 11, 2018) (listing cases). All of the exhibits attached to the RJN are properly subject to judicial notice.

are not considered lifetime devices, and patients likely will undergo implant removal(s)," (3) that "[a]dditional surgeries to the patients' breasts will likely be required," and (4) that patients "will need to have regular MRIs over her lifetime to screen for silent rupture." RJN Ex. D, at 10. Defendant provided similar warnings directly to patients. *See* RJN Ex. E, at 13–16.

Plaintiff's remaining allegations, related to toxic chemicals, radiation, and chemotherapy, fail to establish that Defendant violated a federal requirement. First, the PMA details the extensive toxicity testing completed on Defendant's products, and it concluded that the "gel and shell components . . . did not elicit a toxic response." RJN Ex. C, at 9. Defendant accurately reported the PMA's findings in the Patient Pamphlet, disclosing that "toxicology testing has indicated that the silicone material used in Allergan's implants does not cause toxic reactions." RJN Ex. E, at 19. Second, the PMA does not indicate that patients would require future chemotherapy and radiation after receiving Defendant's breast implants, and Plaintiff fails to direct the Court to any federal requirement to the contrary. *See* RJN Ex. C, at 1–28. Plaintiff cannot hold Defendant to any requirements other than those established by the FDA, because the MDA expressly preempts state requirements that are "different from, or in addition to," federal requirements. 21 U.S.C. § 360(k).

III. Statute of Limitations

In Plaintiff's complaint, she does not disclose when she discovered her injuries, or when she had her breast implants removed. Defendant, however, claims that Plaintiff's counsel disclosed that Plaintiff's breast implants were removed in October of 2017. Def.'s Mot. to Dismiss 14 n.9, ECF No. 8. Plaintiff filed this action on August 24, 2022, more than two years after her implants were allegedly removed. A plaintiff must commence an action connected to an injury from silicone breast implants within two years of discovery. O.R.S. 30.908(1). Assuming Plaintiff knew that her

implants caused her alleged injuries when they were allegedly removed, the statute of limitations likely bars her claims.

Despite the strong likelihood that the statute of limitations bars Plaintiff's claims, the Court will, out of an abundance of caution, allow Plaintiff an opportunity to replead to clarify when she discovered her injuries and provide facts which plausibly allege that Defendant violated a federal requirement.

CONCLUSION

Defendant's Motion to Dismiss (ECF No. 8) is GRANTED. Should Plaintiff choose to file an amended complaint, Plaintiff shall so file within 14 days.

IT IS SO ORDERED.

DATED this 10th day of April, 2023.

/s Michael McShane

Michael J. McShane

United States District Judge